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10/790,289	03/01/2004	Kati A. Chevaux	1010/102US4	9500
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NADA JAIN, P.C. 560 White Plains Road, Suite 460 Tarrytown, NY 10591			EXAMINER WINSTON, RANDALL O	
			ART UNIT	PAPER NUMBER
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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/790,289  
Filing Date: March 01, 2004  
Appellant(s): CHEVAUX ET AL.

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Nada Jain  
For Appellant

**EXAMINER'S ANSWER**

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This is in response to the appeal brief filed February 7, 2008 appealing the Final Office action mailed August 8, 2007.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

5,554,645	Romanczyk, Jr. et al.	9-1996
6,127,421	Wideman, Jr. et al.	10-2000

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 31-74 are rejected under 35 US 103(a) as being unpatentable over Romanczyk, Jr (US 5,554,645) in view of Wideman et al. (6,127,421).

A food product (i.e. non-chocolate) comprising (i) cocoa polyphenol (i.e. a polyphenol compound of formula An of claim 32) and (ii) L-arginine in various amounts is claimed.

Romanczyk teaches (see, e.g. figure 3, column 7 lines 20-27 and entire patent) a food composition comprising a cocoa polyphenol (i.e. a polyphenol compound of formula An of claim 32 is within figure 3 of Romanczyk, named (-) epicatechin) is used for anti-tumor purposes). Romanczyk, however, does not expressly teach that the

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active ingredient of L-arginine is contained within the claimed food composition nor Romanczyk teach all the claimed forms of the food composition and all the claimed amounts/ranges used for anti-tumor purposes.

Wideman beneficially teaches (see, e.g. column 2 lines 30-39) that the incorporation of L-arginine within a food product is used for anti-tumor purposes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Romanczyk's food composition to include the other claimed active ingredient of L-arginine as taught by Wideman within Romanczyk's food composition because the two above combined teachings as a whole would create the claimed food composition used for anti-tumor purposes. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (i.e. the active ingredients of cocoa polyphenol and L-arginine used for an anti-tumor purpose), in order to form a third composition to be used for the same purpose." Furthermore, the adjustment of other conventional working conditions (e.g. determining suitable amounts/ranges of each active ingredient (i.e. cocoa polyphenol and L-arginine) within the claimed composition to intrinsically have some and/or any effective functional effect when administered to a subject and the modification of one form for another of the food composition such as non-chocolate pet food and/or as a peanut), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Please note, the intended use of the above claimed composition (i.e. to induce a physiological increase in nitric oxide) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

#### **(10) Response to Argument**

In regards to the 35 U.S.C. 103(a) rejection based on the combination of Romanczyk, Jr (US 5,554,645) in view of Wideman et al. (6,127,421), appellant argues that as of the effective filing date of the above application, the knowledge in the art as to the anti-tumor/cancer effect of dietary arginine supplementation in mammals was highly controversial and various contradictory reports existed in the field - as discussed in Yeatman (Depletion of Dietary Arginine Inhibits Growth of Metastatic Tumor, Arch. Surg. 1991, 126(11): 1376-92). For example, appellant states that Yeatman refers to 70 years of investigation of the effects of arginine on tumor growth and states that despite these efforts, the effect of dietary arginine on tumor growth had not been clearly

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elucidates and that arginine was shown to both stimulate and inhibit tumor growth (Yeatman, page 1375, col. 1, First paragraph).

Although the teachings of Yeatman have been considered (including previously) by the examiner, the examiner disagrees with appellant's argument. That is, although Yeatman indicates that various contradictory reports exist in the field with respect to arginine supplementation providing an anti-tumor effect in mammals (as argued by appellant), Yeatman expressly teaches that at least some prior art research indicates that such dietary arginine supplementation has demonstrated an anti-tumor/anti-cancer effect. Thus, the teachings of Yeatman would not be persuasive to one of ordinary skill in the art to ignore investigating the use of a composition comprising arginine for treating cancer including a cancerous tumor therewith (since even Yeatman admits that dietary supplementation with arginine had been shown in the prior art to provide such an anti-tumor/anti-cancer effect). Accordingly, the USC 103 rejection is deemed proper for the reasons of record - i.e., as discussed therein, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Romanczyk's non-chocolate cocoa polyphenol-containing anti-tumor food composition to include the other claimed active ingredient of L-arginine as taught by Wideman because the combined reference teachings as a whole would reasonably suggest to the skilled artisan to provide such a composition for anti-tumor purposes. Moreover, as discussed in MPEP Section 2114.06, "it is *prima facie* obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose

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(i.e. the active ingredients of cocoa polyphenol and L-arginine used for an anti-tumor purpose), in order to form a third composition to be used for the same purpose.”

Appellant further argues that in order to make the claimed compositions obvious, combining the procyanidin (cocoa polyphenol) taught within Romanczyk and the arginine taught within Wideman should be effective for increasing nitric oxide (NO) rather than for anti-tumor effects. In other words, the procyanidin (cocoa polyphenol) of Romanczyk and the arginine of Wideman cannot be optimized for NO effects when such effects are not suggested by the cited prior art.

The examiner disagrees with appellant's argument because the intended use of the instantly claimed composition (i.e. to induce a physiological increase in nitric oxide) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the composition reasonably suggested by the combined teachings of the cited references (see, e.g., MPEP 2112). In addition, based upon the beneficial teachings provided by Romanczyk and Wideman, as a whole, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instantly claimed ingredients for anti-tumor purposes. Please note, as discussed in MPEP Section 2114.06, “it is well known to be *prima facie* obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (i.e. the active ingredients of cocoa polyphenol and L-arginine used for an anti-tumor purpose), in order to form a third composition to be used for the same purpose.”



Furthermore, the examiner also disagrees with appellant arguments (i.e., that the cocoa procyanidin/polyphenol taught by Romanczyk and the arginine taught by Wideman cannot be optimized for NO effects when such effects are not suggested by the cited prior art) because the instant specification provides for very broad amount ranges of the instantly claimed ingredients therein - including from about 1  $\mu$ g to about 10 g per unit dose of cocoa polyphenol and of L-arginine therein so as to provide the effect of stimulating nitric oxide production, as well as arresting cancer cells and/or modulating apoptosis (among other effects), in a subject in need thereof (see, e.g., page, 9 lines 4-12, and page 20, lines 13-32, of the instant specification). Accordingly, the amounts of cocoa polyphenol and arginine disclosed by the respective reference teachings (i.e., Romanczyk discloses high levels/percentages of cocoa polyphenol within such non-chocolate food compositions for inhibiting tumor growth; and Wideman discloses the prior art use of an anti-tumor feed composition comprising 0.92% or 2.40% of arginine therein) would intrinsically provide the instantly claimed *in vivo* functional effect with respect to increasing nitric oxide, upon ingestion thereof.

#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Randall O Winston

May 21, 2008

Conferees:

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